

JUL 25 2002

KQ2094  
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## SUMMARY OF SAFETY AND EFFECTIVENESS

**Sponsor:** Biomet, Inc.  
56 East Bell Drive  
P.O. Box 587  
Warsaw, IN 46581-0587

**Contact Person:** Tracy J. Bickel  
(574) 267-6639

**Proprietary Name:** PAR 5 Acetabular Components

**Common Name:** Acetabular Component(s)

**Classification Name:** Hip joint metal/polymer semi-constrained cemented prosthesis (888.3350)

**Substantially Equivalent Devices:** PAR 5 Acetabular Components- K000254

**Device Description:** The PAR 5 Acetabular Component is a hemispherical metallic acetabular cup, which can accept a modular hook, ilium flange, and/or a modular ischial blade. The shell accepts a standard Ringloc® liner. The outer surface of the shells has porous coating. The shells are also available with or without hydroxyapatite (HA) coating.

**Indications:** The indications for the PAR 5 Acetabular Component(s) are as follows:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- 2) Rheumatoid arthritis
- 3) Correction of functional deformity
- 4) Treatment of nonunion, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
- 5) Revision procedures where other treatment or devices have failed

**Summary of Technologies:** Hydroxyapatite coated implants and an additional ilium flange are being added to the current PAR 5 System. The PAR 5 Acetabular Components- the material's, design, sizing, and indications are identical to the predicate device(s).

**Non-Clinical Testing:** Substrate testing with an Engineering Justification determined that the modified PAR 5 Acetabular Components presented no new risks and were, therefore, substantially equivalent to the predicated device.

**Clinical Testing:** None provided as a basis for substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 25 2002

Ms. Tracy J. Bickel  
Regulatory Specialist  
Biomet Orthopedics, Inc.  
P.O. Box 587  
Warsaw, Indiana 46581-0578

Re: K022094

Trade/Device Name: PAR 5 Acetabular Component

Regulation Number: 21 CFR §888.3350

Regulation Name: Hip joint metal/polymer metal semi-constrained cemented prosthesis  
and Hip joint metal/polymer/metal semi-constrained porous-coated  
uncemented prosthesis

Regulatory Class: Class II

Product Code: JDI and LPH

Dated: June 24, 2002

Received: June 27, 2002

Dear Ms. Bickel;

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

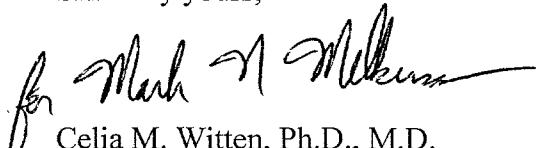
Page 2 – Ms. Tracy J. Bickel

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

510(k) Number (if known): K022094

Device Name: **PAR 5**

Indications for Use:

The indications for the PAR 5 Acetabular component are as follows:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- 2) Rheumatoid arthritis
- 3) Correction of functional deformity
- 4) Treatment of nonunion, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques
- 5) Revision procedures where other treatment or devices have failed

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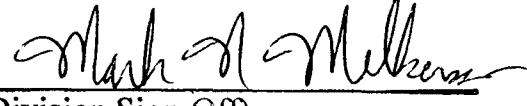
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

  
f \_\_\_\_\_  
(Division Sign-Off)  
Division of General, Restorative  
Medical Devices

S. V. M. K022094

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